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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/541,462 | 03/31/2000 | Yue Xiong | 5470-255 | 3846 |
| 20792 | 7590 | 02/17/2004 | EXAMINER | |
| MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | RAMIREZ, DELIA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------|--------------------------------------|-------------------------------------|--|
| Advisory Action | Application No. 09/541,462 | Applicant(s) XIONG ET AL. | |
| | Examiner Delia M. Ramirez | Art Unit 1652 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 3-6, 13 and 14.

Claim(s) objected to: 1 and 7.

Claim(s) rejected: 15 and 16.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

1. Claims 1, 3-7, 13-17 are pending.
2. Applicant's submission of a new declaration on 10/31/2003 is acknowledged.
3. The request for entering amendments to claims 1, 13, 16, canceling claims 8-12, 17-48, and arguments filed on 1/15/2004 under 37 CFR 1.116 in reply to the Final Action Paper No. 22 mailed on 10/17/2003 are acknowledged. The proposed amendments to the claims will be entered since they are deemed sufficient to overcome the objections and claim rejection under 35 USC 103(a) previously applied. However, entry of these amendments is not deemed sufficient to place the application in condition for allowance for the following reasons.
4. Claim 1 would be objected to due to the recitation of "wherein said nucleic acid encodes a protein that forms.....ligase activity" in item (b) and (c). To clearly indicate that the functional limitation recited refers to the nucleic acids claimed and not to the nucleic acids to which the claimed nucleic acids hybridize/have sequence identity, it is suggested that the functional limitation be recited immediately after the term "(b) a nucleic acid" and "(c) a nucleic acid".
5. Claim 1 would be objected to due to the recitation of "(b) a nucleic acid that hybridizes to the complement of a nucleic acid". To clearly indicate that the term "complement" refers to the entire complement of a nucleic acid, it is suggested that the term be amended to recite "complete complement".
6. Claim 7 would be objected to due to the recitation of "a cell comprising an expression vector according to claim 6 and capable...". Since claim 6 is drawn to a cell, for clarity, it is suggested that the term be amended to recite "a cell according to claim 6 capable....".
7. Claim 15 remains rejected under 35 USC, 112 second paragraph due to the recitation of "expression vector encoding an antisense oligonucleotide" for the reasons of record. Applicant's submission of references by Mohuczy et al. and Weiss et al. have been considered but are not deemed

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persuasive to overcome the rejection previously applied. While it is agreed that the art teaches the use of vectors capable of transcribing antisense fragments to inhibit the production of a target protein by interfering with a target protein's mRNA, as indicated before, as known in the art, nucleic acids "encode" proteins. If the intended meaning of the term is "expression vector capable of transcribing the antisense oligonucleotide of claim 13", the claim should be amended accordingly. For examination purposes, claim 15 has been interpreted to be directed to any vector comprising any polynucleotide encoding a polypeptide of any function wherein the polynucleotide comprises the oligonucleotide of claim 13.

Correction is required.

8. Claims 15 and 16 remain rejected under 35 USC 112, first paragraph, written description and scope of enablement for the reasons of record. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. While Applicants argue that the specification provides adequate written description and is enabling for the oligonucleotide of claim 13 as well as an expression vector, as indicated above, claim 15 has been interpreted to be directed to any vector comprising any polynucleotide encoding a polypeptide of any function, wherein said polynucleotide comprises the oligonucleotide of claim 13. In regard to claim 16, the claim as written is directed in part to a method of producing a genus of proteins of any function comprising a fragment of at least 20 amino acids of the polypeptide of SEQ ID NO: 2 (60 consecutive nucleotides of the polynucleotide of SEQ ID NO: 1). It is reiterated herein that while the specification discloses the structure and function of the polypeptide of SEQ ID NO: 2, and the corresponding polynucleotide (SEQ ID NO: 1), the specification does not provide information as to the functions associated with all the polynucleotides recited in the claims. In addition, the structural limitations recited in regard to the nucleic acids do not constitute a substantial portion of the genera of nucleic acids recited as the remainder of the structure of the nucleic acids recited is completely undefined. Furthermore, the specification fails to disclose which are the critical nucleotides in the polynucleotide of SEQ ID NO: 1 which are essential to encode a protein having

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the same function as that of the polypeptide of SEQ ID NO: 2 and the state of the art as discussed previously teaches the unpredictability of accurately assigning function based solely on structural homology. Thus, for the reasons of record and those set forth above, one cannot reasonably conclude that the specification provides an adequate written description of the claimed invention or is enabling for the full scope of the specification.

9. Claim 15 was rejected under 35 USC 103(a) as being unpatentable over Arino et al. (GenBank accession number CAA99155, August 1997). Amended claim 13, from which claim 15 depends, is now directed to an antisense oligonucleotide that is 12 to 50 nucleotides in length. Since Arino et al. does not teach a polynucleotide which comprises fragments of the polynucleotide of SEQ ID NO: 1 wherein the fragments are 12 to 50 nucleotides in length, this rejection is hereby withdrawn.

10. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: 3-6, 13-14

Claims(s) objected to: 1 and 7

Claim(s) rejected: 15-16

11. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
February 9, 2004


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1652